SEP 2 4 2003

K031971

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510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact Person:	**Tiffani Rogers** Clinical Research Specialist, Product Development Phone: (574) 371-4927 FAX: (574) 371-4987
Trade Name:	**Global CAP Resurfacing Replacement Shoulder**
Common Name:	Resurfacing shoulder
Classification:	**Class II** Device per 21 CFR 888.3690: Shoulder joint, humeral (hemi-shoulder), metallic uncemented prosthesis.
Device Product Code:	**HSD**
Panel:	Orthopaedic
Performance Standards:	No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for humeral shoulder prosthesis.
Substantially Equivalent Devices:	Copeland Shoulder MB/HA Resurfacing Head K010827 DePuy Global Advantage Shoulder K911686 (Formerly the Global Total Shoulder)
Device Description:	The Global CAP Resurfacing Shoulder is a cementless humeral head to be used for the treatment of shoulder joints: • The humeral head is made of ASTM F-75 Cobalt Chrome Molybdenum alloy with a porocoat application on the non-articulating surface and the proximal stem. Curvature sizes are available in 40mm to 56mm (in 4mm increments) with head sizes of 15mm, 18mm and 21mm.

K031971

510(k) Summary (continued)

Indications for use:

The DePuy Global CAP Resurfacing Shoulder is intended as a hemi or total shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device will increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The DePuy Global CAP Resurfacing Shoulder is indicated for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain, non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis), deformity and/or limited motion, fractures of the humeral head and traumatic arthritis.

CAUTION: The DePuy Global CAP Resurfacing Shoulder is intended for cementless use only.

Substantial equivalence:

The DePuy Global CAP Resurfacing Shoulder is manufactured from the same material, sterilized and packaged in the same fashion and has the same intended use and design features as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2003

Ms. Tiffani Rogers
Clinical Research Specialist, Product Development
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K031971
Trade/Device Name: Global CAP Resurfacing Replacement Shoulder
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: June 24, 2003
Received: June 26, 2003

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

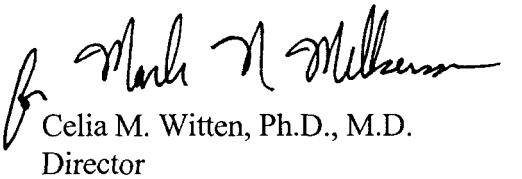
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031971

Device Name: Global CAP Resurfacing Replacement Shoulder

Indications for Use:

The DePuy Global CAP Resurfacing Replacement Shoulder is intended as a hemi or total shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device is designed to increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The DePuy Global CAP Resurfacing Replacement Shoulder is indicated for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain, non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis), deformity and/or limited motion, fractures of the humeral head and traumatic arthritis.

CAUTION: The DePuy Global CAP Resurfacing Replacement Shoulder is intended for cementless use only.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031971

Concurrence of CDRH, Office of Device Evaluation

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109)